Message

From: Epstein, Laura [Laura.Epstein@fda.hhs.gov]
Sent: 1/13/2017 3:49:45 PM
To: Milewski, Elizabeth [Milewski.Elizabeth@epa.gov]; Nalubola, Ritu [Ritu.Nalubola@fda.hhs.gov]
CC: Flamm, Eric [Eric.Flamm@fda.hhs.gov]; Zborowsky, Ashley [Ashley.Zborowsky@fda.hhs.gov]; McNally, Robert [Mcnally.Robert@epa.gov]
Subject: RE: preview of EPA's comment on FDA roll-out materials

We actually are accepting one of your edits on the mosquito QA. The comments we are not taking are the ones in the first paragraph of the response to ***Q. Why is the FDA regulating the Oxitec mosquito, when its intent was clearly to reduce the* Aedes aegypti *mosquito population?***
The added language at the beginning of the first sentence of the 2nd paragraph of that response (i.e., "consistent with FDA's (and EPA's and USDA's) commitment . . . .") we are taking. Farther down in that paragraph, where the additions are deleted, we are not accepting those changes.
I know this is confusing so feel free to call if you want clarification (but email me first as I'm working from home today).

Laura

From: Milewski, Elizabeth [mailto:Milewski.Elizabeth@epa.gov]
Sent: Friday, January 13, 2017 9:56 AM
To: Nalubola, Ritu
Cc: Flamm, Eric; Zborowsky, Ashley; Epstein, Laura; McNally, Robert
Subject: RE: preview of EPA's comment on FDA roll-out materials

Good morning, All.

The text embedded below looks good. Thank you.

With regard to the mosquito QA – just to be clear – FDA is not accepting any of EPA's suggested changes? As I am not a lawyer, and cannot comment on the fine points of law, I will send this on to Chris with the comment that if he feels strongly about his suggestions, he should contact Laura or Ashley to discuss. I will get back to you ASAP.

What is your deadline for getting these materials finalized?

PS – I want to thank you for working with us on these materials, and all the materials developed for the January 19 issuance date, and for being so accommodating to our suggestions. Thank you. It has been a pleasure.

From: Nalubola, Ritu [mailto:Ritu.Nalubola@fda.hhs.gov]
Sent: Thursday, January 12, 2017 11:20 PM
To: Milewski, Elizabeth <Milewski.Elizabeth@epa.gov>
Cc: Flamm, Eric <Eric.Flamm@fda.hhs.gov>; Zborowsky, Ashley <Ashley.Zborowsky@fda.hhs.gov>; Epstein, Laura <Laura.Epstein@fda.hhs.gov>
Subject: RE: preview of EPA's comment on FDA roll-out materials

Elizabeth – We suggest some edits to your alternative text under Q5:

"While FDA has for some time been aware that the emergence of new genetic technologies would drive a need for revision of GFI 187, the agency also determined that it would be appropriate to announce concurrently the availability of draft guidance GFI 236 that clarifies that products intended for preventing, destroying, repelling or mitigating mosquitoes for population control are excluded from the new animal drug definition, including those mosquito-related products with intentionally altered genomic DNA~~that clarifies that intentionally altered~~

~~genomic DNA in mosquitoes would be excluded from GFI 187 when such products are intended for preventing, destroying, repelling or mitigating mosquitoes for population control.~~"

Also, I just realized that we did not send you our reactions to your comments on mosquito QAs – now attached. We didn't have anything on your input on RFI QAs.

I will be out of the office tomorrow so I will leave this to Eric, Laura, and Ashley. Please follow-up with them, as needed.

Thanks!
Ritu

From: Milewski, Elizabeth [mailto:Milewski.Elizabeth@epa.gov]
Sent: Thursday, January 12, 2017 5:30 PM
To: Nalubola, Ritu
Cc: Flamm, Eric; Zborowsky, Ashley; Epstein, Laura
Subject: RE: preview of EPA's comment on FDA roll-out materials

Hi, Ritu. We are ok with most of your revised text, except we would like to make an alternative suggestion to your question 5. Please see the attached file.

I'll be working tomorrow and can be reached at Ex. 6 - Personal Privacy if you think it might be fruitful to talk.

From: Nalubola, Ritu [mailto:Ritu.Nalubola@fda.hhs.gov]
Sent: Thursday, January 12, 2017 3:21 PM
To: Milewski, Elizabeth <Milewski.Elizabeth@epa.gov>
Cc: Flamm, Eric <Eric.Flamm@fda.hhs.gov>; Zborowsky, Ashley <Ashley.Zborowsky@fda.hhs.gov>; Epstein, Laura <Laura.Epstein@fda.hhs.gov>
Subject: RE: preview of EPA's comment on FDA roll-out materials

Hi Elizabeth – Attached are our responses, suggested edits. Copying colleagues.
We still haven't received your comments through the comms channels but will make these edits when we get those.
Let us know if we should discuss.
Thanks!
Ritu

From: Milewski, Elizabeth [mailto:Milewski.Elizabeth@epa.gov]
Sent: Thursday, January 12, 2017 12:21 PM
To: Nalubola, Ritu
Cc: Flamm, Eric
Subject: RE: preview of EPA's comment on FDA roll-out materials

Hi, Ritu. I just sent comment to our comm person to forward to FDA. There are no changes from what I sent you yesterday evening. I am available to talk this afternoon. Just let me know when.

From: Nalubola, Ritu [mailto:Ritu.Nalubola@fda.hhs.gov]
Sent: Thursday, January 12, 2017 9:44 AM
To: Milewski, Elizabeth <Milewski.Elizabeth@epa.gov>
Cc: Flamm, Eric <Eric.Flamm@fda.hhs.gov>
Subject: RE: preview of EPA's comment on FDA roll-out materials

Hi Elizabeth – Many thanks for sharing these as a heads-up! Understood, these are a preview only and formal comments will come in after Chris has reviewed.

We started looking at these and can suggest some alternative text to your 187 edits but we'll hold off until we get the formal set. Your edits on the other documents look doable to me. I or Eric may call you later in the day, if needed, to run our alternative edits by you informally. Looping in Eric.
Thanks again!
Ritu

From: Milewski, Elizabeth [mailto:Milewski.Elizabeth@epa.gov]
Sent: Wednesday, January 11, 2017 8:47 PM
To: Nalubola, Ritu
Subject: preview of EPA's comment on FDA roll-out materials

Hi, Ritu. After our conversation earlier today, I took a stab at suggesting language that I hoped might address EPA's concerns with the QAs on 187 and genome editing. I sent my suggested text to our lawyer, Chris Kaczmarek, for comment, but he has not yet gotten back to me. In addition, EPA will formally send comment through our communication folks to your communication folks. So, theoretically, EPA's formal comment will arrive at your desk sometime tomorrow.

However, given the lateness of the hour and knowing how little time is left before your roll-out materials must be made available to the public, I thought I might send you my mark-up so you can see what I was thinking today. Always being aware that tomorrow's version might be somewhat different depending on what Chris has to say.

I've attached the 3 files on which EPA has comment. We had no comment on materials in the 4th file.

Unfortunately, I am tied up in meetings from 10:00 am to 12:00 pm tomorrow morning, but can be reached at Ex. 6 - Personal Privacy during the rest of the day.